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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/757,433

Applicant(s)

ULBRICHT ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-6,8-14 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-6,8-14 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration filed 11/21/06. Claims 3-6,8-14 and 30 are pending.

#### *Regarding the Amendment to the specification*

1. The amendment filed 09/20/05 remain objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows: Deletion or removal of “one or more” from paragraphs 10 and 22 of the specification introduces new matter to the disclosure. The specification as originally filed does not support deleting/removing “one or more” that identifies the extent of the nonvolatile constituents. The specification as originally filed does not state that the nonvolatile constituents are urea and hydrophilic polymer; specifically, paragraph 23 states “the amounts of urea are in each case based on the **nonvolatile constituents** of the use according to the invention and can be from 35 to 85 percent by weight, from 39 percent by weight to 83 percent by weight, from 46 percent by weight to 63 percent by weight, or from 55 percent by weight to 63 percent by weight.”

Applicant is required to cancel the new matter in the reply to this Office Action.

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims 3-6, 8-14 and 30 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

The recitation that urea is non-volatile has no support in the as filed specification because paragraphs [0010] to [0015] and [0026] to [0031] lists urea as a separate constituent b) from the nonvolatile constituent a).

This rejection can be overcome by amending the claims to be commensurate with the as filed specification. For example, urea is not listed in the as filed specification as one of the constituents of the "one or more nonvolatile constituents."

***Response to Arguments***

4. Applicant's arguments filed 3/14/2006 have been fully considered but they are not persuasive.

Applicant argues that non-volatility of urea is supported by the US pharmacopeia which states "urea is practically odorless, but may develop a slight odor of ammonia upon long standing." That chocolate is non-volatile and cheese are non-volatile and yet have a smell and therefore, examiner is confusing odor with volatility.

**Response:**

Liquids as well and solids may be volatile if they have high vapor pressure or low boiling point. Organic compounds, which evaporate at normal temperature and pressure are considered

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to be volatile. For example, the Merriam-Webster Dictionary defines volatile as “readily vaporizable at low temperatures.” Thus it is not just the same but the ability of a material, organic compounds, solid or liquids that vaporize at low temperatures is volatility. The fact that urea has the chemical formula of  $\text{H}_2\text{NCONH}_2$  does not mean that urea is not volatile because it gives up ammonia upon vaporizing. Ammonia is part of the structure of urea. The melting of urea occurs with decomposition.

However, in the original disclosure urea was not included as one of the “one or more non-volatile constituents” as is described in the application at paragraphs [0010] to [0015]. It is observed that urea is listed separately for the “one or more nonvolatile constituents.”

Therefore, the deletion of “one or more” from the specification introduces new matter into the specification. Regarding defining urea as non-volatile, it is noted that the specification at paragraphs [0010] to [0015] and [0026] to [0031] describes composition that comprises “a) one or more nonvolatile constituents,” “b) urea ... relative to the nonvolatile constituents of the preparation,” c) hydrophilic film-forming agent and d) water or alcohol-water mixture. In the specification therefore, components of the preparation from b-d are separate from a, which is the non-volatile constituent. The specification does not include component b with the non volatile constituents and the specification does not provide any listing of what the nonvolatile components/constituents are. The specification does not include urea as a nonvolatile constituent. On this basis, applicant can not now say that components a) and b) are the same when the specification intended a) and b) as separate components of the preparation. Troetscher et al. in US 6,126,883 discusses that volatile urea vapors as well as dusts are released into the

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atmosphere (column 2, lines 20-25); paragraph [0009] of US 20070042124 recognizes urea as a volatile reagent.

Therefore, the objection to the specification and the rejection of the claims under 35 USC 112, first, is maintained.

***Response to Arguments***

**Previous rejections that are not reiterated herein are withdrawn.**

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-6, 8-14 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laugler et al. (GB 2 202 743) in view of Murdan ("Drug delivery to the nail following topical application," in International Journal of Pharmaceutics, Vol. 236, Issue 1-2, 2 April 2002, pages 1-26) and further in view of Crandall (US 5,639,740).

Laugler in GB 2 202 743 discloses treating fungal infections of nails and surrounding tissues (page 5, 3<sup>rd</sup> full paragraph) by administering composition in the form of a lotion or gel or vanish (page 2, 4<sup>th</sup> full paragraph), the composition comprises in the dissolved state miconazole or econazole in amount of from 1-2% by weight relative to the total weight of the composition

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(page 2, 3<sup>rd</sup> full paragraph and last paragraph), urea in amount of from 1 to 20% relative to the total weight of the composition (page 3, first full paragraph), dissolving intermediary (solvent) and film forming resin (paragraphs 2-5 of page 3), 0.5 to 2% and preferred amount of 0.7-1.5% gelling or thickening agents in the case of gels (page 3, last paragraph to page 4, 1<sup>st</sup> full paragraph), and film forming resin such as polyvinylpyrrolidone/vinyl acetate polymer for varnishes (page 4, 2<sup>nd</sup> full paragraph) with the film forming resin present at from 7.5 to 30%, preferably from 10-20% relative to the total weight of the composition (page 5, 1<sup>st</sup> full paragraph). Varnish meets the limitation of a solution or liquid as recited in claim 30, since varnish can be a liquid or solution and the prior art does not define the varnish as other than a liquid or solution. The film forming resin such as polyvinylpyrrolidone/vinyl acetate polymer meet the limitation of hydrophilic film forming agent of claims 30, 3 and 8. The alcohol in examples I and IV meet the limitations of claims 30 and 9-12 with the ratios or amounts in claims 11 and 12 representing optimizable values. Laugler discloses that the composition when applied hydrates the nail (page 2, first full paragraph).

Crandall discloses method of treating skin, hair, cracked toenails, cracked fingernails, hooves and horns of humans and animals (abstract; column 3, lines 43-45) with moisturizing composition that comprises lecithin, isopropyl palmitate, water, PLURONICS, urea or ceramide or salicylic acid or hyaluronic acid, various alpha hydroxyl-compounds such as lactic acid, citric acid and glycolic acid, gelling agents such as polyvinylpyrrolidone, polyvinyl alcohol and poloxamers (column 4, lines 56-60; column 5, lines 22-28 and 42-51), and stabilizers, antioxidants, preservatives, humectants, antimicrobial agents (column 5, lines 67 to column 6,

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line 7). The lactic acid meets claim 13. Thus, Crandall is relied upon for disclosing method of treating cracked fingernail or toenail with a spray composition, which is a liquid, that can contain lactic acid or citric acid and the lactic acid appear to present at amounts of 0.01% to 1% meeting claim 14; the inclusion of the lactic acid may further aid in moisturizing keratinous materials according to Crandall (column 5, lines 13-31).

Examples I and IV of Laugler disclose compositions in the form of varnish. As admitted in applicant's remarks filed 11/21/06, the amount of urea in example IV is about 38.5% relative to the non-volatile constituents when urea is included as a non-volatile constituent. Urea in Example IV will be 62.5 if urea is not included with the non-volatile constituents. For example I, the % film forming polymer cannot be the 40% because the first full paragraph of page 5 of Laugler (the GB reference) states that the film forming polymer is at from 7.5 to 30%, with a preferred % of from 10-20% relative to the total weight of the composition. Furthermore, a 50% strength of the polymer composition is used so that the 40% polymer resin in example I translates to about 20% or less, which places % urea at about 29% if urea is included with the non-volatiles and about 41% if excluded. Thus, urea at about 29% or 38.5%, relative to the total weight of the non-volatiles including urea, is used by Laugler.

The difference between Laugler and claim 30 is % amount of the urea. Laugler discloses about 29 and 38.5% while claim 30 requires from 41 to 69% of urea. However, there is no demonstration that the recited range of 41-69% provides unexpected results and from 41 to 69 represents 1.7fold increase. Regarding the amount of urea, it is known in the art that as much as 40% urea is used to treat diseased nails (see first full paragraph, left column of page 6 of Murdan). Therefore, it would have been obvious to one of ordinary skill in the art at the time



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the invention was made to use the varnish composition of Laugler to treat fungal infections of the nail. One having ordinary skill in the art would have been motivated to optimize the amount of urea in the composition of Laugler as is evidenced from Laugler and Murdan, that would be expected to effectively treat fungal infections of the nail.

7. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Response to Arguments***

8. Applicant's arguments filed 11/21/06 have been fully considered but they are not persuasive.

Applicant's argument regarding 41% in the claims vs. 38.46% in Laugler is moot as it regards the anticipatory rejection.

However, applicant's argument as regards the current rejections is not persuasive because:

a) The range of urea recited in the claims represent optimizable amounts, there is about 1.7 fold increase from 41 to 69% in the claims and optimization of say a about 38.5% by a 1.7 would yield about 65.4, and optimization of 29% by 1.7 would yield 49.3,

b) Murdan discloses the use of up to 40% urea for treating fungal infections of the nails,

c) While Eudragit is an insoluble polymer, the polyvinylpyrrolidone/vinyl acetate and polyvinylpyrrolidone are few one of the polymers recited in claim 30.

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The claims are rendered obvious by the GB reference in combination with Murdan and Crandall.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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